K000885

SEP 26 2000

METRIKA

Metrika, Inc.
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Sunnyvale, CA 94086
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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K000885.

807.92 (a)(1): Name: Metrika, Inc.
Address: 510 Oakmead Parkway
Sunnyvale, CA 94086
Phone: (408) 524-2255
FAX: (408) 524-2252
Contact: Joel M. Blatt, Ph.D.

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name: DRx® HbA1c for prescription home use

Common Name: percent hemoglobin A1c (percent glycosylated hemoglobin)

Classification: assay, glycosylated hemoglobin 21 CFR 864.7470
This test is WAIVED under CLIA '88.

807.92 (a)(3): Identification of the legally marketed predicate device

The DRx® HbA1c test is substantially equivalent to Tosoh A1c 2.2 Plus Automated Glycohemoglobin Analyzer (Tosoh Medics, Inc., South San Francisco, CA).

807.92 (a)(4): Device Description

The DRx® HbA1c test is a four-channel reflectance photometer that incorporates microelectronics, optics, and dry-reagent chemistry strips within a self-contained, integrated, single-use device. An unmeasured whole blood mixture (diluted) is directly applied to the sample port, and results are displayed in numeric form on the device's liquid crystal display after eight minutes. Having no switches or buttons, the device self-activates upon addition of the sample.

807.92 (a)(4): Device Description (continued)

The DRx® HbA1c device utilizes both immunoassay and chemistry technology to measure HbA1c and total hemoglobin, respectively. Upon the addition of a diluted blood sample, blue microparticles conjugated to anti-HbA1c antibody migrate along the reagent strips. The amount of blue microparticles captured on the strips reflects the amount of HbA1c in the sample.

For the total hemoglobin portion of the assay, the dilution of sample converts Hb to met-Hb, which is red-brown in color. The intensity of the red-brown color measured on the reagent strips is proportional to the concentration of hemoglobin in the sample.

807.92 (a)(5): Intended use

The DRx® HbA1c test provides the quantitative measurement of the percent of glycated hemoglobin (% HbA1c) levels in fingerstick (capillary) whole blood samples. The test is for prescription home use by individuals with diabetes to monitor glycemic control.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

Similarities Between DRx® HbA1c and Tosoh A1c 2.2 Plus

CHARACTERISTIC	DRx® HbA1c	Tosoh A1c 2.2 Plus
Intended Use	Quantitative measurement of the percent of glycated hemoglobin	Quantitative measurement of the percent of glycated hemoglobin
Indications for Use	Used in the management and treatment of diabetes, for monitoring long term glycemic control	Used in the management and treatment of diabetes, for monitoring long term glycemic control
Risk to Patient	Not a critical analyte - reflects glucose monitoring over time	Not a critical analyte – reflects glucose monitoring over time
Sample	Whole blood	Whole blood
Visual Display	LCD readout	LCD readout
Hemolysate Preparation	Manual (Sample Dilution Kit)	Automated (≥1 ml whole blood sample) or Manual (<1 ml whole blood sample)
Calibration	Not required by end-user; each unit is factory calibrated	2 point at required intervals
Methodology	Immunoassay	Ion-exchange HPLC
Detection Method	Four-channel reflectance photometer	Visible wavelength detector
Testing Environment	Prescription home use	Professional use
Throughput	8 minutes per sample - can run multiple samples simultaneously	3 minutes per sample - must run one sample at a time
User Input	None - Sample addition initiates analysis	Done via pressure sensitive LCD

The differences in the two testing platforms do not raise new issues of safety and effectiveness.

807.92 (b)(1): Brief Description of Nonclinical Data

Studies were performed that evaluated linearity, hematocrit tolerance, specificity, and precision. The DRx® HbA1c test is linear between 3% and 15% HbA1c. The test produces suitable results with hematocrits between 20% and 60% PCV (packed cell volume), and the assay is not affected by high levels of various biological compounds, various common over-the-counter therapeutics, and oral antihyperglycemic agents. The test's imprecision, when testing was performed at three diabetes clinics with multiple lots and multiple operators, was below 10% CV. When following the specific National Glycohemoglobin Standardization Program (NGSP) protocol, the test's total within-laboratory imprecision was about 8%.

807.92 (b)(2): Brief Description of Clinical Data

In studies with over 250 untrained subjects, the accuracy of the DRx® HbA1c- test was, on average 98%, as compared to an NGSP-certified laboratory method. Individual %HbA1c results may differ from a laboratory-derived %HbA1c result by as much as –1.6 %HbA1c to +1.4 %HbA1c. This represents the 95% confidence interval of a Bland-Altman plot. NGSP-certified laboratory methods may show a similar difference at the clinically important level of 7% HbA1c.

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

The DRx® HbA1c test was evaluated for nonclinical and clinical performance characteristics in comprehensive studies. Because of its low bias, the DRx® HbA1c test approximates NGSP-specified overall performance even though it is not within NGSP limits for precision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 26 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Erika B. Ammirati, R.A.C., MT (ASCP)
Clinical/Regulatory Consultant to Metrika, Inc.
Metrika, Inc.
510 Oakmead Parkway
Sunnyvale, California 94086

Re: K000885
Trade Name: DRx® HbA1c - for Prescription Home Use
Regulatory Class: II
Product Code: LCP
Dated: August 30, 2000
Received: August 31, 2000

Dear Ms. Ammirati:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): K000885

Device Name: DRx® HbA1c-Prescription Home Use

Indications for Use:
The DRx® HbA1c test provides quantitative measurement of the percent of glycated hemoglobin (% HbA1c) levels in fingerstick (capillary) whole blood samples. The test is for prescription home use by individuals with diabetes to monitor glycemic control.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000885

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over –the-Counter Use ___
(Per 21 CFR 801.109)